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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/014,087	01/27/1998	WENDA C. CARLYLE	1416.25US01	4103

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EXAMINER	
PREBILIC, PAUL B	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/014,087	CARLYLE ET AL.	
	Examiner	Art Unit	
	Paul B. Prebilic	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-11,14,15 and 21-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-11,14 and 21-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/27/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on September 23, 2004 has been entered.

Double Patenting

> The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
>
> A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).
>
> Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 9, 14, 21, and 29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8, 10, 13, 15, 34, 35, and 38-40 of copending Application No. 09/186,810. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the copending claims is so similar to the

present claimed subject matter that the claim sets read on each other such that they are at least clearly obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States..

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Cahalan (US 5,308,641). Cahalan anticipates the claim language wherein the human or animal tissue is used as the solid surface and the biomolecule is one of the growth factors listed on column 6, lines 14-18; also see the abstract, column 4, lines 20-43, and column 6, lines 8-28. It is noted that "fixed" and "crosslinked" are synonymous in the tissue graft implant art. Furthermore, glutaraldehyde is disclosed as one of the crosslinking agents of Cahalan; see column 4, lines 58-62. When it contacts the tissue

solid surface, it inherently crosslinks it resulting in a crosslinked or fixed tissue as claimed.

Claims 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Bayne et al (EP 0476983), or alternatively, under 35 USC 103(a) as being unpatentable over Bayne et al alone.

Bayne anticipate the claim language wherein the fibrin coating is applied prior to or in addition to the VEGF II growth factors to the surface of the fixed umbilical cord vein; see the abstract, page 8, lines 14-26, and in particular, page 8, lines 20-23. The Examiner posits that the tubular supports coated with VEGF II include fixed umbilical cord vein, and thus, the claim language is fully met. The attachment of cells to the vessel is done prior to implantation such that the claim language requiring growth factor associated with the tissue is fully met.

Alternatively, if one does not consider the tubular supports coated with VEGF II as including umbilical cord vein, than the claim language is not fully met. However, the Examiner posits that it would have been clearly obvious to use umbilical cord vein as the tubular support since it is used as an implant in another procedure; it would bring the desired features of tissue properties to the implant site. Furthermore, a combination of proteins, such a fibrin, and growth factor (VEGF II) would have been at least obvious in view of Bayne alone since the teaching of doing the same are all contained in the same paragraph and there is no clear delineation between them.

Claims 1-2, 4-5, 9-11, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bayne et al (EP 0476893) in view of Wadstrom (US 5,631,011).

Bayne et al discloses an implant having a fibrin coating (a biologic adhesive as claimed), which is applied prior to the VEGF II growth factor (VEGF II is the polypeptide growth factor as claimed). The fixed umbilical cord vein of Bayne et al is the substrate for coating as claimed; see page 8, lines 14-26. However, the Bayne et al cord vein, although a crosslinked human or animal tissue, is not clearly either an allograft or xenograft as claimed. In other words, the tissue of Bayne is generic to both allograft and xenograft tissues Nonetheless, it is the Examiner's position that it would have been considered clearly obvious to an ordinary artisan to use an allograft or xenograft tissue for the cord vein of Bayne et al absent some showing of criticality therefor.

Wadstrom is cited to show that fibrin is a common biologic tissue adhesive in the art (see the abstract and column 1, lines 1-20), and thus, the fibrin coating of Bayne et al can be called and would function as a biologic adhesive as claimed.

Claims 6-8, 14, 15, 21-24, and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bayne et al and Wadstrom as applied to claims 1-5, 9-11, and 29 above, and further in view of Carpentier (US 4,648,881). Bayne et al fails to disclose uncrosslinked tissue, the heart valve form of the tissue, or the other tissue types as claimed. However, Carpentier teaches that all uncrosslinked and crosslinked forms of tissue, heart valve tissue forms and other types of tissue are all well known in the art; see column 2, lines 3-15. Hence, it is the Examiner's position that it would have been obvious to use any of these materials as the substrate of Bayne et al for the applications contemplated by Carpentier. One would be motivated to form Bayne et al implants into other shapes in order to make it useful in other sites and broaden its applicability.

Response to Arguments

Applicant's arguments filed September 23, 2004 have been fully considered but they are not persuasive.

Double Patenting Rejection

Applicants argue that claims 14 and 29 have been amended to eliminate covalent bonding with crosslinking agents. However, there are still three other common ways of associating the growth factor with the substrate in the claims of both the present application and the copending application; in addition, both claim sets include tissue and growth factor of varying scope. For this reason, the Examiner asserts that the claim sets are obvious in view of each other. Upon review of the claim sets, it was determined that the claim sets clearly overlap to the extent that they are obvious in view of each other.

It is noted that Applicants have offered to file a terminal disclaimer if the claims are allowed.

Section 102 Rejection over Cahalan

Applicants argue that Cahalan's disclosure is directed to attaching polyalkylimine to a substrate and not to crosslink the tissue and attach an exogenous agent. In response, the Examiner asserts that all the claim limitations are met so the Cahalan's overall purpose for the invention is not relevant. In addition, once Cahalan attaches polyalkylimine to the tissue, it becomes part of the tissue. For this reason, at least the polyalkylimine treated tissue is crosslinked, and thus, the claim language is fully met with this interpretation. Furthermore, even if one does not agree that crosslinked

polyalkylimine treated tissue constitutes crosslinked tissue as claimed, the Examiner asserts that the crosslinking treatment would also inherently crosslink the tissue protein to some extent. This is due to the fact that the protein of tissue reacts with aldehyde molecules to form crosslinked bonds; see Example 1 of Carpentier et al (US 4,648,881). Finally, the Examiner asserts that the fact that Cahalan is concerned with attaching spacer molecules to a substrate does not mean the disclosure thereof does not anticipate the claim language.

Section 102/103 rejection over Bayne

Applicants argue that Bayne is directed to two distinct embodiments even though these embodiments are all part of the same paragraph of Bayne's disclosure. Again, the Examiner asserts that Bayne or any prior art document need not be completely directed to crosslinked tissue with an exogenous growth factor in order to anticipate the claims. Since Bayne has all the claim features, as explained in the rejection, the Examiner maintains that the claims are anticipated thereby.

It is noted that Bayne is quite broad in his application of vascular endothelial cell growth factor II. For example, it is disclosed for use as a medicament (see claim 14), as a treatment for synthetic polymeric vessels (see *supra* and claims 16 and 17), and for use in vascular repair (see claim 17 and page 8, lines 27-37). Clearly, Bayne teaches treatment of a implant with VEGF II prior to implantation and discloses that the implant can be fixed tissue. For these reasons, the Examiner asserts that it would have been at least clearly obvious to use this growth factor on fixed umbilical vein.

Section 103 rejection over Bayne, Wadstrom and Carpentier

Applicants argue that Bayne does not disclose the use of a biologic adhesive. In response, the Examiner maintains that the rejection fully explains how fibrin is considered to be an adhesive to the extent that this language can be given patentable weight. In other words, the claim language is fully met in this regard because it has all the properties and functions of an adhesive. Wadstrom is cited to show that the art even considers fibrin a biologic adhesive. Applicants are clearly attacking Wadstrom individually and are not concerned with how it is being applied in the combination of references.

Applicants argue that Wadstrom teaches that fibrin is not an adhesive on column 1, lines 17-28. In response, the Examiner does not see any suggestion of that in the cited passage or elsewhere. Rather, Wadstrom clearly teaches that fibrin is an adhesive; see column 1, lines 17-20. Furthermore, the Applicants' own specification states that fibrin is a type of adhesive; see page 13, lines 15-20 of the present specification. Additionally, Bayne teaches that fibrin and other proteins "enhance attachment of cells to the artificial surface"; see page 8, lines 21-23. For these reasons, the Examiner asserts that fibrin in an adhesive to the extent that this language can be given patentable weight.

In response to the argument that there is no motivation to combine Wadstrom with Bayne, the Examiner asserts that Wadstrom is used to show that fibrin is an biologic adhesive as claimed. Since Wadstrom is merely teaching an inherent feature of Bayne, it is not required to have a motivation any more than a dictionary definition is

required to have a motivation for its use. Furthermore, since Wadstrom is in the same art of vascular tissue repair as that of Bayne, the Examiner asserts that the motivation for relying on Wadstrom is the same as the reason Wadstrom uses the same material in the art.

In response to the traversal that there is no motivation to combine Carpentier with Bayne, the Examiner notes that the motivation is clearly set forth in the rejection as "[o]ne would be motivated to form Bayne et al implants into other shapes in order to make it useful in other sites and broaden its applicability." Furthermore, Bayne is drawn to all types of vascular tissue repair. Carpentier is directed to specific repair of, preferably, tissue heart valves. Tissue heart valves are types of vascular grafts. For this reason, one in the art would clearly look to Carpentier to see some specific uses of the tissue repair composition of Bayne.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 3738